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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,949	06/07/2006	Magne Solbakken	PN0302	6745
36335 7590 06/08/2009 GE HEALTHCARE, INC. IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231				
EXAMINER				
SCHLIENTZ, LEAH H				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
06/08/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,949

Applicant(s)

SOLBAKKEN ET AL.

Examiner

Leah Schlientz

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7 and 9-11 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 3/27/2009, in reply to the Office Action mailed 10/27/2008, is acknowledged and has been entered. Claim 1 has been amended. Claim 12 is newly added. Claim 4 has been cancelled. Claims 1,7 and 9-12 are pending and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments filed 3/27/2009 have been fully considered. New grounds of rejection are set forth herein based upon further consideration of the claims.

Double Patenting

Claims 1, 7 and 9-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 7,431,914, for reasons set forth in the previous Office Action.

Applicant's Response at pages 7-8 indicates that a terminal disclaimer will be filed once the present Application is allowed. However, since no terminal disclaimer has been filed the claims stand rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a compound of general formula 1: V-L-Z or a pharmaceutically acceptable salt thereof, wherein V is a non-peptidic vector having affinity for the Angiotensin II receptor and is selected from Losartan, Valsartan, Candesartan, Eprosartan or derivatives thereof.

The claims are unclear as to what may be encompassed by the term "derivatives." While the specification provides a description of a single specific Losartan derivative based on attachment of Linker (L) and imaging moieties (Z) to the imidazol 5 position at paragraph 0047, or an azide-derivative of Losartan at paragraph 0048, it is unclear what types of further "derivatization" may be performed on Losartan, Valsartan, Candesartan, Eprosartan such that would represent "derivatives thereof" to be within the scope of the claims. The broadest reasonable interpretation of derivatives of a compound covers all future improvements without regard to whether Applicants invented such improvements, which would undermine the function of the claims because it would allow Applicants to benefit from the ambiguity, rather than requiring Applicants to give proper notice of the scope of the claims to competitors. Additionally, adopting the broadest reasonable construction of the claims could retard innovation because cautious competitors may steer too far around that which Applicants actually invented, neglecting improvements that otherwise

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might be made. See *Halliburton Energy Services Inc. v. M-I LLC*, 85 USPQ2d 1654 (Fed. Cir. 2008). Accordingly, the metes and bounds of the claims are not clearly set forth and the scope of the invention cannot be distinctly ascertained.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a pharmaceutical composition comprising an effective amount of a compound of general Formula (1) or a salt thereof, together with one or more pharmaceutically acceptable adjuvants, excipients or diluents. However, where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See MPEP § 608.01(m). See also 2173.05(s).

In the instant case, it is respectfully suggested that the claim be amended such that it is dependent upon claim 1, such as reciting "a pharmaceutical

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composition comprising an effective amount of a compound of claim 1 or a salt thereof, together with one or more pharmaceutically acceptable adjuvants, excipients or diluents" or similar language.

Claim Objections

Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS